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EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	**PAPER NUMBER**
3771	

NOTIFICATION DATE	DELIVERY MODE
03/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/537,085	KING, MICHAEL L.	
	Examiner	Art Unit	
	Annette F. Dixon	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/8/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed on September 8, 2008. Examiner acknowledges claims 1-34 are pending in this application, with no amendments or cancelled claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-9, 13, 14, 16, 20, 24, and 27-30 are rejected under 35 U.S.C. 102(a/e) as being anticipated by von Schuckermann (6,401,712).

As to Claims 1, 27, and 28, von Schuckermann discloses an oral inhaler (Figure 4) for delivering a pharmaceutical formulation to a patient, said inhaler comprising a container (2, Figure 17) having the pharmaceutical formulation comprising at least one medicament (9) present therein; and a mouthpiece (17) configured for oral engagement

with a patient and in communication with said container (2, Figure 17), the mouthpiece (17) having an inner surface (defined by the space within 31) and an outer surface (defined by the external portion of the mouthpiece); wherein the outer surface of the mouthpiece (17) contains at least one longitudinally-extending disuniformity (18) such that when the patient orally engages the mouthpiece (17) at least one void space is created between the outer surface of the mouthpiece (17) and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament to the patient. Regarding the longitudinally extending disuniformity. von Schuckermann discloses a plurality of longitudinally extending disuniformities. Further, the term “longitudinally extending disuniformity" does not provide a measure of the length of the disuniformity. Regarding the limitation of the air flow channel, the ability of air to flow across the mouthpiece is a function of the sealing of the patient's mouth along the mouthpiece, and also the position of the mouthpiece within the patient's mouth.

As to Claims 2-9, von Schuckermann discloses a plurality of longitudinally extending disuniformities (18) (Figure 11). Regarding the protrusions (Claims 3-7), the peaks of the disuniformities (18) on the mouthpiece (17) can broadly be interpreted as protrusions. Regarding the indentations (Claims 8-9), the valleys of the disuniformities (18) on the mouthpiece (17) can broadly be interpreted as indentations.

As to Claims 13, 14, 16, 29, and 30, von Schuckermann discloses the medicament includes a multitude of inhalable medicaments for conveying hormones,

antihistamines, antibiotics etc. Further, von Schuckermann discloses the use of specific drugs such as salmeterol. (Column 3, Line 64 thru Column 4, Line 28).

As to Claim 20, von Schuckermann discloses a blister pack (2). Inherently the blister pack provides a metered dose to the patient. (Figure 17).

As to Claim 24, von Schuckermann discloses the dispersal of medicament in a blister pack utilizing power formulations. (Abstract).

4. Claims 1-9, 13, 20, 24-26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Ambrosio et al. (5,394,868).

As to Claims 1 and 28, Ambrosio discloses an oral inhaler (Figures 22, 38, 47, and 49) for delivering a pharmaceutical formulation to a patient, said inhaler comprising a container having the pharmaceutical formulation comprising at least one medicament present therein (Column 2, Lines 46-67); and a mouthpiece (292) configured for oral engagement with a patient and in communication with said container, the mouthpiece (292) having an inner surface (292p) and an outer surface (292h) (Figure 39); wherein the outer surface (292h) of the mouthpiece (292) contains at least one longitudinally-extending disuniformity (the sloped mouthpiece that slopes back and along the longitudinal axis of the inhaler as seen in Figures 22, 23, 38, 39, 47 and 49) such that when the patient orally engages the mouthpiece (292) at least one void space is created between the outer surface of the mouthpiece (292) and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament to the patient. Regarding the longitudinally extending

disuniformity. Ambriosio discloses a plurality of longitudinally extending disuniformities. Further, the term “longitudinally extending disuniformity" does not provide a measure of the length of the disuniformity. Regarding the limitation of the air flow channel, the ability of air to flow across the mouthpiece is a function of the sealing of the patient's mouth along the mouthpiece, and also the position of the mouthpiece within the patient's mouth.

As to Claims 2-9, Ambrosio discloses a plurality of longitudinally extending disuniformities (the sloped mouthpiece that slopes back and along the longitudinal axis of the inhaler as seen in Figures 22, 23, 38, 39, 47 and 49). Regarding the protrusions (Claims 3-7), the region adjacent the indentation disuniformities (the sloped mouthpiece that slopes back and along the longitudinal axis of the inhaler as seen in Figures 22, 23, 38, 39, 47 and 49) presents a raised or protruded region along the mouthpiece (292). Regarding the indentations (Claims 8-9), the disuniformities (the sloped mouthpiece that slopes back and along the longitudinal axis of the inhaler as seen in Figures 22, 23, 38, 39, 47 and 49) on the mouthpiece (292) indents along the length of the inhaler.

As to Claims 13, 20, 24, 25, and 26, Ambrosio discloses the medicament (Column 6, Lines 30-35) in a metered powder dose dispenser (10), wherein the medicament delivered contains a desiccant. (Column 18, Lines 9-25).

5. Claims 1-9 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Conway (6,536,423).

As to Claims 1 and 28, Conway discloses an oral inhaler (Figures 1-3) for delivering a pharmaceutical formulation (water) to a patient, said inhaler comprising a container (142) having the pharmaceutical formulation (water) comprising at least one medicament present therein; and a mouthpiece (102) configured for oral engagement with a patient and in communication with said container (Figure 1), the mouthpiece (102) having an inner surface (represented by the internal tubing of aperture 128) and an outer surface (106); wherein the outer surface (106) of the mouthpiece (102) contains at least one longitudinally-extending disuniformity (the projected and indented sections as seen in Figures 3 and 6) such that when the patient orally engages the mouthpiece (102) at least one void space is created between the outer surface (106) of the mouthpiece (102) and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament to the patient. Regarding the longitudinally extending disuniformity. Conway discloses a plurality of longitudinally extending disuniformities. Further, the term “longitudinally extending disuniformity" does not provide a measure of the length of the disuniformity. Regarding the limitation of the air flow channel, the ability of air to flow across the mouthpiece is a function of the sealing of the patient's mouth along the mouthpiece, and also the position of the mouthpiece within the patient's mouth.

As to Claims 2-9, Conway discloses a plurality of longitudinally extending disuniformities (the projected and indented sections as seen in Figures 3 and 6).

6. Claims 1-9, 13, 20, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Datta et al. (5,871,010).

As to Claims 1 and 28, Datta discloses an oral inhaler (Figures 8a and 8b) for delivering a pharmaceutical formulation to a patient, said inhaler comprising a container (86) having the pharmaceutical formulation comprising at least one medicament present therein (87, Column 8, Lines 22-34); and a mouthpiece (94) configured for oral engagement with a patient and in communication with said container, the mouthpiece (94) having an inner surface (defined by arrows, Figures 8a and 8b) and an outer surface (the mouth contacting region); wherein the outer surface (the mouth contacting region) of the mouthpiece (94) contains at least one longitudinally-extending disuniformity (the series of air inlets 82 and channels 83) such that when the patient orally engages the mouthpiece (94) at least one void space is created between the outer surface of the mouthpiece (94) and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament to the patient. Regarding the longitudinally extending disuniformity. Detta discloses a plurality of longitudinally extending disuniformities. Further, the term “longitudinally extending disuniformity" does not provide a measure of the length of the disuniformity. Regarding the limitation of the air flow channel, the ability of air to flow across the mouthpiece is a function of the sealing of the patient's mouth along the mouthpiece, and also the position of the mouthpiece within the patient's mouth.

As to Claims 2, 10-12, Datta discloses a plurality of longitudinally extending disuniformities (the series of air inlets 82 and channels 83) thereby providing a plurality of openings along the longitudinal axis of the mouthpiece (94)

As to Claims 13, and 20, Datta discloses the medicament (Column 8, Lines 22-34) in a metered powder dose (Column 8, Lines 35-39).

7. Claims 1-13, 20, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Howlett (6,062,214).

As to Claims 1, 13, and 28, Howlett discloses an oral inhaler (Figure 1) for delivering a pharmaceutical formulation to a patient, said inhaler comprising a container (12) having the pharmaceutical formulation comprising at least one medicament (Column 2, Lines 55-59) present therein; and a mouthpiece (14) configured for oral engagement with a patient and in communication with said container (12), the mouthpiece (14) having an inner surface (defined by the space containing the arcuate arrows, Figure 1) and an outer surface (defined by the external portion of the mouthpiece); wherein the outer surface of the mouthpiece (14) contains at least one longitudinally-extending disuniformity (protrusion from the opening of the mouthpiece to the rest of the housing seen in Figure 6 and holes 23) such that when the patient orally engages the mouthpiece (14) at least one void space is created between the outer surface of the mouthpiece (14) and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament to the patient Regarding the longitudinally extending disuniformity, Howlett

discloses a plurality of longitudinally extending disuniformities. Further, the term "longitudinally extending disuniformity" does not provide a measure of the length of the disuniformity. Regarding the limitation of the air flow channel, the ability of air to flow across the mouthpiece is a function of the sealing of the patient's mouth along the mouthpiece, and also the position of the mouthpiece within the patient's mouth.

As to Claims 2-12, Howlett discloses a plurality of longitudinally extending disuniformities (protrusion from the opening of the mouthpiece to the rest of the housing seen in Figure 6 and holes 23). Regarding the protrusions (Claims 3-7), the peaks of the disuniformities (protrusion from the opening of the mouthpiece to the rest of the housing seen in Figure 6) on the mouthpiece (14) can broadly be interpreted as protrusions. Regarding the indentation, the portion of the mouthpiece (14) prior to the protrusion as seen in Figure 6, can be construed to be a indentation of the mouthpiece (14) in a longitudinal direction. Regarding the openings (Claims 10-12), Howlett discloses a plurality of holes (23) on the mouthpiece (Figure 1) that extend to a through the mouthpiece to the medicament inlet.

As to Claim 20, Howlett discloses a metered dose inhaler (MDI) with an MDI canister. (Figure 1).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 15, 17-19, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Schuckermann (6,401,712) in view of Davies (6,553,987).

As to Claims 15, 17-19, and 31-34, von Schuckermann discloses a powder inhaler, yet does not expressly disclose an extensive listing of alternative medicaments available to be inhaled in powder form. However, at the time the invention was made an extensive list of alternative medicaments including the recited compositions was known. Specifically, Davies teaches an extensive listing of medicaments including the recited medicaments (Column 8, Lines 25-67) as alternative and preferred medicaments (Preferred Agents: beclomethasone dipropionate, fluticasone propionate, albuterol, and salmeterol) to be utilized in the delivery of medicaments to the patient's respiratory tract. Therefore, it would have been obvious to one having ordinary skill in the art the time the invention was made to modify the powder inhaler of von Schuckermann to dispense alternative medicaments known to be helpful as taught by Davies to provide respiratory treatment to a patient.

10. Claims 14-19, 27, and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ambrosio et al. (5,394,868) in view of Davies (6,553,987).

As to Claims 14-19, 27, and 29-34, Ambrosio discloses a powder inhaler, yet does not expressly disclose an extensive listing of alternative medicaments available to be inhaled in powder form. However, at the time the invention was made an extensive list of alternative medicaments including the recited compositions was known.

Specifically, Davies teaches an extensive listing of medicaments including the recited medicaments (Column 8, Lines 25-67) as alternative and preferred medicaments (Preferred Agents: beclomethasone dipropionate, fluticasone propionate, albuterol, and salmeterol) to be utilized in the delivery of medicaments to the patient's respiratory tract. Therefore, it would have been obvious to one having ordinary skill in the art the time the invention was made to modify the powder inhaler of Ambrosio to dispense alternative medicaments known to be helpful as taught by Davies to provide respiratory treatment to a patient.

11. Claims 1, 2, 10-13, 20, 24, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newhouse (5,113,855).

As to Claims 1 and 28, Newhouse discloses an oral inhaler (309) for delivering a pharmaceutical formulation to a patient, said inhaler comprising a container (42) having the pharmaceutical formulation (74) comprising at least one medicament present therein (Column 6, Lines 4-6); and a mouthpiece (48) configured for oral engagement with a patient and in communication with said container, the mouthpiece (48) having an inner surface (represented by the tail of the arrow in Figure 5) and an outer surface (the mouth contacting region); wherein the outer surface (the mouth contacting region) of the mouthpiece (48) contains at least one disuniformity (holes, 54) such that when the patient orally engages the mouthpiece (48) at least one void space is created between the outer surface of the mouthpiece (48) and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the

at least one medicament to the patient. Regarding the limitation of the air flow channel, the ability of air to flow across the mouthpiece is a function of the sealing of the patient's mouth along the mouthpiece, and also the position of the mouthpiece within the patient's mouth. Regarding the longitudinally extending disuniformity. Newhouse discloses a plurality of longitudinally extending disuniformities. Further, the term “longitudinally extending disuniformity" does not provide a measure of the length of the disuniformity. Yet Newhouse does not expressly disclose the shape of the holes in a longitudinal extending manner. However, it would have been an obvious matter of design choice to make the different portions of the holes of whatever form or shape was desired or expedient. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

As to Claims 2, 10-12, Newhouse discloses a plurality of longitudinally extending disuniformities (the sloped mouthpiece that slopes back and along the longitudinal axis of the inhaler as seen in Figures 22, 23, 38, 39, 47 and 49).

As to Claims 13, 20, and 24, Newhouse discloses the medicament ((Column 6, Lines 4-6) in a metered powder dose dispenser (10).

12. Claims 14-19, 27, and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newhouse (5,113,855) in view of Davies (6,553,987).

As to Claims 14-19, 27, and 29-34, Newhouse discloses a powder inhaler, yet does not expressly disclose an extensive listing of alternative medicaments available to

be inhaled in powder form. However, at the time the invention was made an extensive list of alternative medicaments including the recited compositions was known. Specifically, Davies teaches an extensive listing of medicaments including the recited medicaments (Column 8, Lines 25-67) as alternative and preferred medicaments (Preferred Agents: beclomethasone dipropionate, fluticasone propionate, albuterol, and salmeterol) to be utilized in the delivery of medicaments to the patient's respiratory tract. Therefore, it would have been obvious to one having ordinary skill in the art the time the invention was made to modify the powder inhaler of Newhouse to dispense alternative medicaments known to be helpful as taught by Davies to provide respiratory treatment to a patient.

13. Claims 14-19, 27, and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Datta et al. (5,871,010) in view of Davies (6,553,987).

As to Claims 14-19, 27, and 29-34, Newhouse discloses a powder inhaler, yet does not expressly disclose an extensive listing of alternative medicaments available to be inhaled in powder form. However, at the time the invention was made an extensive list of alternative medicaments including the recited compositions was known. Specifically, Davies teaches an extensive listing of medicaments including the recited medicaments (Column 8, Lines 25-67) as alternative and preferred medicaments (Preferred Agents: beclomethasone dipropionate, fluticasone propionate, albuterol, and salmeterol) to be utilized in the delivery of medicaments to the patient's respiratory tract. Therefore, it would have been obvious to one having ordinary skill in the art the time the

invention was made to modify the powder inhaler of Newhouse to dispense alternative medicaments known to be helpful as taught by Davies to provide respiratory treatment to a patient.

14. Claims 14-19, 21-24, 27, and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howlett (6,062,214) in view of Ashurst (6,532,955)

As to Claims 14-19, 21-24, 27, and 29-34, Howlett discloses an inhaler, yet does not expressly disclose an extensive listing of alternative medicaments available to be inhaled with a propellant. However, at the time the invention was made an extensive list of alternative medicaments including the recited compositions was known. Specifically, Ashurst teaches an extensive listing of medicaments including the recited medicaments (Column 2, Line 1 thru Column 5, Line 50) as alternative medicaments (beclomethasone dipropionate, fluticasone propionate, albuterol, and salmeterol) to be utilized in the delivery of medicaments to the patient's respiratory tract. Therefore, it would have been obvious to one having ordinary skill in the art the time the invention was made to modify the powder inhaler of Howlett to dispense alternative medicaments known to be helpful as taught by Ashurst to provide respiratory treatment to a patient.

Response to Arguments

15. Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bacaner et al. (4,966,141) discloses an additional mouthpiece having holes (150 and 151). Hougen (5,890,998) discloses an additional mouthpiece having protrusions and indents. Rubin (6,539,939), Salter et al. (5,584,285), Durkin et al. (6,230,704), Gupte et al. (5,676,130), and Ohki et al. (5,715,811) disclose additional inventions having mouthpieces with intends or protrusions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771

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/Justine R Yu/
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